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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,205	03/24/2004	Suzanne T. Ildstad	17541-040001	3925

26191 7590 08/28/2006

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EXAMINER	
GIBBS, TERRA C	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,205	IIDSTAD, SUZANNE T.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending in the instant application.

Claims 1-30 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 2, 7-12, 14, 15, 17-24, 26, and 27, drawn to a method for conditioning a recipient for bone marrow transplantation, comprising administering to said recipient a composition that specifically depletes αβ-, and γδ- TCR$^+$ T cells and/or CD8$^+$ T cells in the recipients hematopoietic microenvironment, followed by a delayed transplantation with a donor cell preparation containing hematopoietic stem cells from a donor that are matched at the major histocompatibility complex class I K locus with the recipient hematopoietic microenvironment, wherein the composition comprises antibodies specific for αβ-, and γδ- TCR$^+$ T cells and/or CD8$^+$ T cells, and combination therapy thereof, classifiable in class 424, subclass 9.34.

Group II. Claims 3-5, 7-12, 14, 15, 17-24, 26, and 27, drawn to a method for conditioning a recipient for bone marrow transplantation, comprising administering to said recipient a composition that specifically depletes αβ-, and γδ- TCR$^+$ T cells and/or CD8$^+$ T cells in the recipients hematopoietic microenvironment, followed by a delayed transplantation with a donor cell preparation containing hematopoietic stem cells from a donor that are matched at the major histocompatibility complex class I K locus with the recipient hematopoietic microenvironment, wherein the composition comprises

antisense DNA directed against the precursors of αβ-, and γδ- TCR$^+$ T cells and/or CD8$^+$ T cells, and combination therapy thereof, classifiable in class 435, subclass 375.

Group III. Claims 6-12, 14, 15, 17-24, 26, and 27, drawn to a method for conditioning a recipient for bone marrow transplantation, comprising administering to said recipient a composition that specifically depletes αβ-, and γδ- TCR$^+$ T cells and/or CD8$^+$ T cells in the recipients hematopoietic microenvironment, followed by a delayed transplantation with a donor cell preparation containing hematopoietic stem cells from a donor that are matched at the major histocompatibility complex class I K locus with the recipient hematopoietic microenvironment, wherein the composition comprises a small cytotoxic drug specific for αβ-, and γδ- TCR$^+$ T cells and/or CD8$^+$ T cells, and combination therapy thereof, classifiable in class 514, subclass 2.

Group IV. Claims 28-30, drawn to a method for conditioning a recipient for bone marrow transplantation, comprising subjecting said recipient to a total dose of total body irradiation and infusing the recipient with a donor cell preparation containing hematopoietic stem cells from the donor following total body irradiation, classifiable in class 600, subclass 310.

Claims 1, 13, 16, and 25 links inventions of Groups I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1, 13, 16, and 25. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if

any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions do not overlap in scope, since Groups I-IV each comprise the use of different structures, such as genes (i.e. DNA), proteins (i.e. antibodies or peptides) and/or photon irradiation. Further, Groups I-III have different steps related to administering a composition that specifically depletes $\alpha\beta$-, and $\gamma\delta$- TCR^+ T cells and/or $CD8^+$ T cells in the recipients hematopoietic microenvironment, which is not shared by Group IV and therefore Groups I-III do not overlap in scope with Group IV. Groups I-IV are materially distinct methods, which differ in reagents and/or dosages and/or schedules used, response variables, and criteria for success. Because these groups have unique structures or unique steps not shared by any other group, the inventions are also therefore not obvious variants, and

have at least a materially different design. Since it is a burden to search and examine these multiple inventions in a single application due to the fact that the searches are divergent and non-coextensive, restriction is proper therefore.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: diabetes, multiple sclerosis, sickle cell, anemia, hematologic malignancy, and immunodeficiency. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 17, 22, and 24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg
August 23, 2006